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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,173	05/16/2005	Claude Mialhe	0518-1149	5752
466	7590	08/18/2008	EXAMINER	
YOUNG & THOMPSON 209 Madison Street Suite 500 ALEXANDRIA, VA 22314			DANG, PHONG SON H	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/535,173		MIALHE, CLAUDE	
	Examiner		Art Unit	
	SON DANG		4166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/16/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1- 7 are rejected under 35 U.S.C. 102(b) as being anticipated by US PG PUB 2001/0037053 to Bonadio et al. (Bonadio).

In Reference to Claim 1:

Bonadio teaches:

Occlusive device (1, Fig. 1) for medical or surgical use, comprising a hollow cylindrical element (outer sleeve 11(a), Fig. 2) that can be twisted (outer sleeve 11 is capable of twisting since the inner sleeve is twisting (Fig. 5, page 3, paragraph 83, lines 8-10)) according to its axis to create a striction zone, comprising a transverse compression deformable body (the inner sleeve of 11(b), Fig. 2) applied to the inner wall of the cylindrical element (the inner sleeve 11(b) is inside of the outer sleeve 11 (a), Fig. 2), and comprising a through hole (12, Fig. 5, page 3, paragraph 83, lines 8-10) according to axis of the cylindrical element (11, Fig. 1).

In Reference to Claim 2:

Bonadio teaches:

Device according to claim 1 (see rejection of Claim 1 above),

wherein the deformable body (the inner sleeve of 11(b), Fig. 2) is attached to the inner wall of the cylindrical element (outer sleeve 11 (a), Fig. 2).

In Reference to Claim 3:

Device according to claim 1 (see rejection of Claim 1 above), wherein the deformable body (the inner sleeve of 11(b), Fig. 2) is made from a polymer material (page 3, paragraph 84, lines 4-5).

In Reference to Claim 4:

Device according to claim 1 (see rejection of Claim 1 above), comprising two end parts (10 and 21, Fig. 4, page 3, paragraph 84, lines 7-9), surrounding the cylindrical element (outer sleeve 11(a), Fig. 2) and whose angular position determines the torsion (Any angle inherently determines the torsion) of said cylindrical element (11, Fig. 5).

In Reference to Claim 5:

Device according to claim 1 (see rejection of Claim 5 above), wherein cylindrical element (outer sleeve 11(a), Fig. 2) and the deformable body (the inner sleeve of 11(b), Fig. 2) both have circular cross sections (They both have cylindrical body therefore both inherently have circular cross sections).

In Reference to Claim 6:

Vascular occlusion device (1, Fig. 1, this device is capable of being

used for vascular occlusion), comprising the occlusive device (1, Fig. 1) according to claim 1 (see rejection of Claim 1 above).

In Reference to Claim 7:

Device according to claim 6 (see rejection of Claim 6 above), comprising two end parts (10 and 21, Fig. 4, page 3, paragraph 84, lines 7-9), surrounding the cylindrical element (outer sleeve 11(a), Fig. 2) and whose relative angular position determines the torsion (any angle inherently determines the torsion) of said cylindrical element (outer sleeve 11(a), Fig. 1), said end parts (10 and 21, Fig. 4, page 3, paragraph 84, lines 7-9) possessing means of attachment to the wall of a vessel.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonadio in view of US Patent No. 5,843,160 to Rhodes (Rhodes).

In Reference to Claim 8:

Bonadio teaches:

Device according to claim 7 (see rejection of Claim 7 above).

Bonadio fails to teach:

The device wherein the attachment means are expanding elements.

Rhodes teaches:

The device (20, Fig. 1) wherein the attachment means are
expanding elements (34, 36, Fig. 1, Col. 8, line 25)

It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the expanding element of Rhodes in place of the Bonadio attachment means because the modification would have been considered a mere substitution of attachment means.

In Reference to Claim 9:

Bonadio as modified by Rhodes teaches:

Device according to claim 8 (see rejection of Claim 8 above).

Where Rhodes teaches:

The device (20, Fig. 1) comprising a seal (30, Fig. 1, Col. 9, lines 34-41) on the outer surface of at least one of the expanding elements (36, Fig. 1, Col. 8, line 25) said seal being appropriate for application to the wall of a vessel.

In Reference to Claim 10:

Bonadio as modified by Rhodes teaches:

Device according to claim 8 (see rejection of Claim 8 above),
comprising a peripheral obturation web (Fig. 26, after the inner sleeve 210 get twisted, it formed a funnel like shape) extending from one end of the deformable body (Fig. 26, the edge that is proximal to O-ring 205)

and the edge (Fig. 26, the edge that is proximal to O-ring 210) of the expanding element (201, Fig. 26).

5. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonadio in view of US Patent No. 7,008,439 to Janzen et al. (Janzen).

In Reference to Claim 11:

Bonadio teaches:

Device according to claim 6 (see rejection of Claim 6 above).

Bonadio fails to teach:

The device comprising a removable guide positioned according to the axis of the cylindrical element and crossing the hole in the deformable body.

Janzen teaches:

The device comprising a removable guide (15, Fig. 14, Col. 4, line 49) positioned according to the axis of the cylindrical element (Fig. 15, the sleeve cover sheath 45) and crossing the hole (Fig. 15, diameter of sheath 45) in the deformable body (45, Fig. 15, Col. 5, line 7).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the removable guide as taught by Janzen in the device of Bonadio for the benefit of guiding of the position for the occlusion device.

In Reference to Claim 12:

Bonadio as modified by Janzen teaches:

Device according to claim 11 (see rejection of Claim 11 above),

Where Janzen teaches:

Device comprising a removable sheath (17, Fig. 15, Col. 4, line 49) inserted between the wall of the hole (Fig. 15, diameter of sheath 45) in the deformable body (45, Fig. 15, Col. 5, line 7) and the outer wall of the guide (15, Fig. 14, Col. 4, line 49).

In Reference to Claim 13:

Bonadio teaches:

Device according to claim 6 (see rejection of Claim 6 above).

Bonadio fails to teach:

The device comprising a removable sleeve surrounding the occlusive device.

Janzen teaches:

The device comprising a removable sleeve (Fig. 15 & 20, the sleeve covering sheath 45) surrounding the occlusive device (plug 93, Fig. 17, Col.8, line 64).

It would be obvious to one having ordinary skill in the art at the time of the invention to have used the sleeve of Janzen for containing and delivering of the occlusive device of Bonadio because the modification would have facilitated implantation of the occlusive device of Bonadio.

6. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonadio in view of US Patent No. 4,580,573 to Quinn (Cited by the applicant).

In Reference to Claim 14:

Bonadio teaches:

An occlusive device (1, Fig. 1) according to claim 1 (see rejection of Claim 1 above).

Bonadio fails to teach:

Valve for surgical or medical instrument, comprising a closeable passage.

Quinn teaches:

Valve (Fig. 1) for surgical or medical instrument, comprising a closeable passage (Col. 2, lines 63-65, Col. 4, lines 55-60).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the device structure of Quinn with the occlusive device of Bonadio because the modification would have advantageously produce an occlusive device to prevent fluid leakage as suggested by Quinn (see Col. 2, lines 63-65).

In Reference to Claim 15:

Bonadio as modified by Quinn teaches:

Valve according to claim 14 (see rejection of Claim 14 above), wherein cylindrical element (11, Fig. 1) can be twisted by means of two

rings (20, 10, Fig. 1-2), each of which is integral to one end of the cylindrical element (11, Fig. 1).

CONCLUSION

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: de la Torre et al. US Patent No. 5,957,913 teaches a laparoscopic access port for surgical instruments having rings, valve and cylindrical structure; Pantages et al. US PG PUB No. 2003/0158578 A1 teaches a sheath apparatus for delivering a closure device having cylindrical sheath and valve structure.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SON DANG whose telephone number is (571)270-5809. The examiner can normally be reached on Monday-Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ken Bomberg can be reached on 571-272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4166

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SD

/Kenneth Bomberg/

Supervisory Patent Examiner, Art Unit 4166